

Appl. No. 09/492,361

**REMARKS**

The claims have been amended to better describe the invention. Support for the amendment to claim 1 can be found on page 23, lines 35-37. Support for the amendment to claim number 59 and for new claim 62 can be found in the Specification on page 23, lines 33-34.

No new matter has been added.

Sequence Rules

The Examiner indicates that sequences appear in Table 1, pages 10-12 of the Specification, but are not identified by SEQ ID NO. as required.

Applicants filed a Preliminary Amendment on March 3, 2000, which amended the table description of Table 1 that appears on page 12, beginning at line 33, to clearly indicate that Human KCNQ1 is SEQ ID NO. 33, Human KCNQ2 is SEQ ID NO. 34, Human KCNQ3 is SEQ ID NO. 35 and Human KCNQ4 is SEQ ID NO. 2. Applicants respectfully submit that this amendment satisfies 37 C.F.R. 1.821(d).

Claim Objections

The Examiner has objected to claim 7 as being in improper dependant form for failing to further limit the subject matter of a previous claim.

Appl. No. 09/492,361

Applicants have canceled claim 7, thereby overcoming the objection.

Rejections Under 35 U.S.C. § 112, first paragraph

*Enablement*

The Examiner has rejected claims 1-4, 7, 10-11, 18, 21-30 and 59-61 for lack of enablement. The Examiner indicates that the claim does not require that the instantly claimed polynucleotide encode a polypeptide which has the function of a potassium channel.

Applicants have amended claim 1 to clearly indicate that the isolated polynucleotide of the invention is a sub-unit of a KCNQ4 potassium channel which, when joined with other subunits, makes up a functional potassium channel. Beginning on page 13, line 27, the Specification indicates that the KCNQ channels described to date function physiologically as heteromers. The description then goes on to indicate that KCNQ4 can interact with other subunits, such as KCNQ3. The Specification gives a specific example of co-expression of KCNQ3 with KCNQ4 to produce a functional potassium channel that has increased current amplitudes as compared to a channel formed of KCNQ3 subunits only. In view of this, Applicants respectfully submit that the amendment to claim 1 makes clear that the isolated polynucleotide of the instant invention encodes a functional

Appl. No. 09/492,361

subunit that is capable of joining with other subunits to produce a functional potassium channel. In view of this, Applicants request reconsideration and removal of the rejection.

The Examiner has rejected claims 10 and 21 for lack of enablement, indicating that no guidance is provided as to which residues are critical for function and which mutations can be made while retaining function.

Applicants have canceled claims 10 and 21, thereby overcoming the rejection.

The Examiner has rejected claim 26 for lack of enablement, indicating that while the Specification is enabled for a host cell in culture or a *Xenopus* oocyte, it does not provide enablement for *in vivo* transfection or a mammalian oocyte comprising SEQ ID NO. 1.

Applicants have canceled claim 26, thereby overcoming the rejection.

#### *Written Description*

The Examiner has rejected claims 1-4, 7, 10-11, 18, 21-30 and 59-61 for lack of written description. The Examiner contends that the Specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The Examiner notes, however, that clarification of the claim such that it was clear that the polynucleotide encoded a

Appl. No. 09/492,361

polypeptide which functions as a potassium channel would obviate this rejection.

Applicants have amended claim 1 as discussed above, to clearly indicate that the polynucleotide of the invention encodes a functional sub-unit that, when joined with other subunits, makes up a functional potassium channel. Thus, Applicants respectfully request reconsideration and removal of the rejection.

The Examiner has rejected claims 10 and 21 for lack of enablement because no guidance is provided to which residues are critical for function and which mutations can be made while retaining function.

Applicants have canceled claims 10 and 21 thereby overcoming the rejection.

Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 29 as being indefinite and incomplete for omitting essential steps. The Examiner identifies the essential step as the isolation step after the final recited step of recovering the cultured cell.

Applicants have amended claim 29 to clearly indicate that after recovering the cultured cells, the KCNQ4 sub-unit is then isolated. Thus, Applicants respectfully request reconsideration and removal of the rejection.

Appl. No. 09/492,361

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claim 28 as being anticipated by U.S. 5,300,634 (Murphy et al.). The Examiner contends that the '634 patent discloses a method for purification of surface exposed antigen of *H. influenzae* that is conserved among strains. The Examiner reasons that since the transfected host cell of claim 28 reads on bacterial cells and bacterial cells transfected with an expression vector will not insert the expressed protein into the membrane, the membrane preparation of the '634 patent anticipates the claim.

Applicants have amended claim 28 to depend from new claim 62. Claim 62 indicates that the polypeptide encoded by the heterologous polynucleotide is incorporated into the cell membrane. As a consequence, claim 28 as amended cannot read on the membrane preparation of the '634 patent. Thus, Applicants respectfully request reconsideration and removal of the rejection.

In view of the above remarks, all of the claims remaining in the case are submitted as defining non-obvious, patentable subject matter.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Gerald M. Murphy, Jr. (Reg.

Appl. No. 09/492,361

No. #28,977) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH &amp; BIRCH, LLP

By  30,350  
Gerald M. Murphy, Jr. (#28,977)

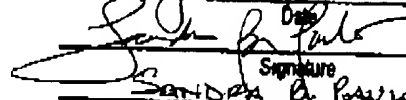
P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

GMM/SWG/sbp  
2815-0127P

**FAX RECEIVED**  
**AUG 20 2003**  
**GROUP 1600**

Certificate of Transmittal  
I hereby Certify that this correspondence is being  
facsimile transmitted to the Patent and  
Trademark Office:

On August 11, 2003

  
Signature  
Sandra A. Pardo  
Typed or printed name of person signing certificate

**OFFICIAL**